

REMARKS

Claims 1, 5-10, 17, 39, and 48 have been amended. Claims 4, 11, 12, and 29 have been canceled.

Reconsideration of the application is respectfully requested in view of the following responsive remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

In the Office Action of November 3, 2005 the following actions were taken:

- (1) The specification was objected to since the abstract was not presented on a separate sheet of paper;
- (2) Claims 39 and 48 were objected to as being in improper dependent form;
- (3) Claims 5-10 were rejected under 35 U.S.C. 112, second paragraph, as having insufficient antecedent basis;
- (4) Claims 10 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, claim 10 recites to two different metals in the chelate;
- (5) Claims 1-4 were rejected under 35 U.S.C. 102 as being anticipated by an academic article entitled "Infrared Spectra of Aqueous Solutions. I. Metal Chelate Compounds of Amino Acids" published in the Journal of the American Chemical Society authored by Kazuo Nakamoto, Yuki Yoshi Morimoto, and Arthur E. Martell (JACS, 1961 83(22), 4528-4532) (hereinafter "Nakamoto");
- (6) Claims 1-4 and 12 were rejected under 35 U.S.C. 102 as being anticipated by an academic article entitled "Metal Chelating Tendencies of Glutamic and Aspartic Acids" published in the Journal of Physical Chemistry authored by R. F. Lumb and A. E. Martell (J. Phys. Chem., 1953 57(7), 690-693) (hereinafter "Lumb");
- (7) Claims 1-5, 17-19, 27-29, 34-36, 41-45, and 50-51 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Pat. No. 5,504,055 (hereinafter "Hsu");
- (8) Claims 1-5, 11, 17, 20-22, 26-29, 34-36, and 41-45 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Pat. No. 6,426,424 (hereinafter "Ashmead '424'");
- (9) Claims 1-4, 17-22, 24-29, 43-45, and 50-51 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Pat. No. 4,725,427 (hereinafter "Ashmead '427'");

(10) Claims 20-23 was rejected under 35 U.S.C. 103(a) as being unpatentable over Hsu in view of U.S. Pat. No. 6,299,896 (hereinafter "Cooper");

(11) Claims 1, 13-17, and 30-33 were rejected under 35 U.S.C. 103(a) as being unpatentable over Ashmead '427 in view of an academic article entitled "Production and Utilization of Amino Acids" published in Angewandte Chemie International Edition authored by Yoshiharu Izumi, Ichiro Chibata, and Tamio Itoh (Angew. Chem. Int. Ed. Engl. 17, 176-183) (hereinafter "Izumi");

(12) Claims 34, 37-40, 43 and 46-49 were rejected under 35 U.S.C. 103(a) as being unpatentable over Hsu in view of Izumi;

(13) Claim 34 was provisionally rejected under the judicially created doctrine of obvious-type double patenting as being unpatentable over claim 17 of copending Application No. 10/969584; and

(14) Claims 1-13, 17-30, 33-37, 40-46, and 49-51 were provisionally rejected under the judicially created doctrine of obvious-type double patenting as being unpatentable over claim 1-13, 19-33, 38-42, 44-46, 48-51, and 53-54 of copending Application No. 10/828,827.

It is respectfully submitted that the presently pending claims be allowed based on the remarks below.

Objection to the Abstract

The Examiner has objected to the abstract as not commencing on a separate sheet in accordance with 37 C.F.R. 1.52(b)(4). On the last page of this response (after the signature page), the Applicant has provided a separate sheet which includes the abstract in compliance with 37 C.F.R. 1.52(b)(4). As such, the Applicant respectfully requests that this objection be withdrawn.

Claim objections and Rejections under 35 U.S.C. § 112, second paragraph

The Examiner has objected to claims 39 and 48 as being as in improper dependent form. Specifically, claims 39 and 48 are alleged to be composition claims which do not further limit the method claims from which they depend. Claims 5-10 were rejected under 35 U.S.C. 112, second paragraph, as having insufficient antecedent basis. Claim 10 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, claim 10 recites to two different metals in the chelate.

Claims 5-10, 39, and 48 have been amended to correct antecedent basis issues, typographical errors, etc., as found by the Examiner. Therefore, the Applicant respectfully requests that these rejections be withdrawn.

Rejections Under 35 U.S.C. § 102

The Examiner has rejected claims 1-5, 11-12, 17-22, 24-29, 34-36, 41-45, and 50-51 as being anticipated by several references. Before discussing the rejection, it is thought proper to briefly state what is required to sustain such a rejection. It is well settled that "[a] claim is anticipated only if each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 2 U.S.P.Q. 2d 1051, 1053 (Fed. Cir. 1987). In order to establish anticipation under 35 U.S.C. 102, all elements of the claim must be found in a single reference. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986), *cert. denied* 107 S.Ct. 1606 (1987). In particular, as pointed out by the court in *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 220 U.S.P.Q. 303, 313 (Fed. Cir. 1981), *cert denied*, 469 U.S. 851 (1984), "anticipation requires that each and every element of the claimed invention be disclosed in a prior art reference." "The identical invention must be shown in as complete detail as is contained in the...claim." *Richardson v. Suzuki Motor Co.* 9 U.S.P.Q. 2d 1913, 1920 (Fed. Cir. 1989). As the Examiner has rejected the four independent claims, two composition claims and two method claims, a discussion of these claims is provided.

Composition Claims 1 and 17

The Examiner has rejected claim 1 and 17 by several general amino acid chelate references; specifically, Lumb, Nakamoto, Hsu, Ashmead '424, and Ashmead '427. However, none of the references set forth a non-GMO metal amino acid chelate composition. This being stated, the Applicant has further amended the composition claims to provide that the amino acid chelates have an amino acid to metal molar ratio from about 2:1 to 3:1, and the chelates are fully coordinated. The Lumb and Nakamoto references do not meet this definition. Specifically, the Lumb and Nakamoto references clearly identify waters of hydration in their reaction schemes as opposed to a fully coordinated chelate. See Lumb, page 4532, and Nakamoto, page 693.

Furthermore, there is considerable doubt that either of these references formed chelates at all. Actual experimental conditions that are used to make these "chelates" is

sparse at best. Nakamoto merely states “[m]ost of the compounds were prepared by standard procedures,” giving no further guidance. See page 4529, Experimental Section.

Additionally, Lumb never states how exactly the chelate forms, instead he explains how he calculates the stability constants for his alleged chelates through potentiometric determination. See page 690. In fact, in the abstract, Lumb discloses that the “probable” structures of the chelates are “suggested.” See page 690. It is unclear if the chelates were supposedly formed from the metal chloride and glutamic and aspartic acid solutions. See page 690, col. 2.

In light of the Ashmead ‘427 patent, it is doubtful that Nakamoto or Lumb created a true chelate, since Ashmead states “in order for a true chelate to be formed the mole ratio of protein hydrolysate ligand or amino acid ligand to metal must be at least 2:1 and the reaction conditions must favor the formation of a chelate by the removal of potentially interfering protons.” See col. 5, lines 59-63. Ultimately, it is clear that neither Lumb nor Nakamoto teach fully coordinated chelates, and therefore, the Applicant respectfully requests that these rejections be withdrawn.

Additionally, the Hsu, Ashmead ‘424, and Ashmead ‘427 references fail to teach non-GMO chelate compositions. In fact, the references never mention GMO or non-GMO at all. As these references have publication dates that are well within the time period where genetically modified organisms were prevalent, these patents clearly teach of chelates, in fact, include chelates and related compositions that could be formed as GMO compositions. The Applicant has claimed a specific narrow class of chelates. The chelates must contain non-GMO components. As the Examiner has not provided a single reference that contains each and every element of the present invention, the Applicant respectfully requests that the Examiner withdraw the current 102 rejections.

Method Claims 34 and 43

The Examiner has rejected claim 34 and 43 over several general amino acid chelate references; specifically, Hsu, Ashmead ‘424, and Ashmead ‘427. However, none of these references provide a method of preparing or administering a non-GMO metal amino acid chelate composition. Independent claims 34 and 43 specifically require an affirmative step of making a non-GMO determination for the metal and for the amino acid. Further, the final product must also be non-GMO, which according to the definition in the specification of non-

GMO, is quite limiting. Relevant portions of the definitions from the specification are provided herein for the Examiner's convenience, as follows:

The term "GMO" is an acronym for the term "genetically modified organism(s)."

The term "GMO derivative" applies to any substance produced from, but not containing a genetically modified organism.

The term "non-GMO" herein includes compositions that are not GMOs, and also are not derived from GMOs. In other words, non-GMO compositions are not genetically modified of themselves, and are prepared by processes other than those which include the use of genetically modified organisms. Thus, amino acid chelates prepared in accordance with embodiments of the present invention, such as for human, animal, or foliar application, must not include or be produced with the utilization of genetically modified organisms.

None of the references provided by the Examiner refer to any such affirmative step of determination as required by claims 34 and 43, and further, as the final product must also be non-GMO, there is no teaching or suggestion in any of the references that the chelates described therein unambiguously meet this criteria. As such, the Applicant has not amended the two independent method claims or subsequent dependent claims to require fully coordinated chelates. Therefore, the Applicant respectfully requests that current 102 rejections be withdrawn.

As the Applicant has explained the novelty of the independent claims over the prior art, the Applicant respectfully requests that the Examiner withdraw the 102 rejections for the corresponding dependent claims as well.

Rejections Under 35 U.S.C. § 103

The Examiner has rejected claims 1, 13-17, 30-34, 37-40, 43 and 46-49 under 35 U.S.C. 103(a) as being unpatentable over combinations of several references.

Applicant does not deem it necessary to recite the entire case law standard required in order to establish a *prima facie* case of obviousness. However, Applicant, would like to briefly remind the Examiner of the required three criteria for a *prima facie* case of obviousness, namely that the asserted references as modified or combined must: 1) teach or

suggest each and every element of the claimed invention; 2) provide sufficient motivation for the modification or combination asserted; and 3) provide a sufficient likelihood of successfully making the modification or combination.

Emphasis on the four independent claims is provided herein, as the Applicants assert that these claims are all patentably distinct over the prior art. Specifically, the Examiner has rejected claims 1, 13-17, 30-34, 37-40, 43 and 46-49 as being obvious in view various combinations of prior art. As the Examiner has rejected the four independent claims, two composition claims and two method claims, a discussion of these claims is provided as follows.

Composition Claims 1 and 17

The Examiner has combined two references, specifically Ashmead '427 and Izumi, to reject claims 1, 13-17, and 30-33. As previously discussed Ashmead '427 does not teach a non-GMO chelate composition. Additionally, Izumi does not teach a non-GMO chelate composition. No showing of any such language in any reference in the current office action has been made to make out a *prima facie* case of obviousness. Therefore, the Applicant respectfully requests that the corresponding 103 rejection be withdrawn.

Method Claims 34 and 43

The Examiner has combined two references, specifically Hsu and Izumi, to reject claims 34, 37-40, 43, and 46-49. As previously discussed, neither Hsu nor Izumi teach a non-GMO chelate composition. Additionally, the Examiner has failed to show any such language in any reference in the current office action related to affirmative steps to select non-GMO materials for use in preparing the non-GMO chelates. As such, no combination references cited by the Examiner teach or suggest every element of the claimed invention. Therefore, the Applicant respectfully requests that the corresponding 103 rejection be withdrawn.

Double Patenting

The Examiner has provisionally rejected Claim 34 under the judicially created doctrine of double patenting over Applicant's copending U.S. Patent Application serial no. 10/969,584. Without conceding the correctness of the rejection and for the sole purpose of advancing prosecution in the present application, Applicant has enclosed herewith is a terminal disclaimer disclaiming the terminal portion of any patent issuing from the present

application which extends beyond that of any patent to issue from U.S. Patent Application serial no. 10/969,584. Applicant submits that such terminal disclaimer renders the issue of double patenting moot and therefore requests that the rejection be withdrawn.

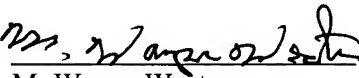
Additionally, the Examiner has provisionally rejected Claims 1-13, 17-30, 33-37, 40-46, and 49-51 under the judicially created doctrine of double patenting over Applicant's copending U.S. Patent Application serial no. 10/828,827. Without conceding the correctness of the rejection and for the sole purpose of advancing prosecution in the present application, Applicant has enclosed herewith is a terminal disclaimer disclaiming the terminal portion of any patent issuing from the present application which extends beyond that of any patent to issue from U.S. Patent Application serial no. 10/828,827. Applicant submits that such terminal disclaimer renders the issue of double patenting moot and therefore requests that the rejection be withdrawn.

Conclusion

In view of the foregoing, Applicants believe that claims 1-3, 5-10, 12-28, and 29-53 present allowable subject matter and allowance is respectfully requested. If any impediment to the entry of the present amendment and reconsideration of the claims in view thereof remains which could be removed during a telephone interview, the Examiner is invited to telephone Mr. Gary Oakeson of this office, or in his absence, M. Wayne Western, so that such issues may be resolved as expeditiously as possible.

Please charge any additional fees except for Issue Fee or credit any overpayment to Deposit Account No. 20-0100.

Dated this 3rd day of March, 2006. Respectfully submitted,


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